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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/693,205	10/20/2000	Thomas J. Hudson	2825.1021-003	7268

21005 7590 02/25/2002

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/693,205	HUDSON ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-12 and 23, drawn to an isolated nucleic acid, a nucleic acid construct and a host cell, classified in class 536, subclass 23.5, and class 435, subclasses 320.1 and 325.

II. Claim 13, drawn to a method for preparing a polypeptide encoded by a nucleic acid, classified in class 435, subclass 69.1.

III. Claims 14, 15, 19 and 20, drawn to an isolated polypeptide encoded by a nucleic acid, classified in class 530, subclass 350.

IV. Claims 16, 21 and 22, drawn to an antibody, which specifically binds to the polypeptide, classified in class 424, subclass 130.1.

V. Claims 17 and 24-33, drawn to a method for assaying the presence of a nucleic acid molecule in a sample and for diagnosing a neurodegenerative disease in an individual, comprising obtaining a nucleic acid sample from the individual and determining the nucleotide present at position 5254 or whether there is a deletion of a thymine at position of 6594 of SEQ ID NO:1, classified in class 435, subclass 6.

VI. Claim 18, drawn to a method for assaying the presence of a polypeptide in a sample, comprising contacting the sample with an antibody, which specifically binds to the polypeptide, classified in class 424, subclass 130.1.

VII. Claims 34 and 35, drawn to a method of treating a neurodegenerative disorder associated with the presence of a thymine at position 5254 of SEQ ID NO:1 or with a

deletion of a thymine at position of 6594 of SEQ ID NO:1 in an individual, comprising administering a nucleic acid molecule which encodes SEQ ID NO:2 or an active portion of SEQ ID NO:2; a polypeptide of SEQ ID NO:2, or, an agonist of SEQ ID NO:2, classified in class 514, subclass 44 (nucleic acid administered), and class 514, subclass 2+ (polypeptide administered).

VIII. Claims 36-39, drawn to a method of diagnosing a neurodegenerative disease associated with the presence of a thymine at position 5254 of SEQ ID NO:1 or with a deletion of a thymine at position of 6594 of SEQ ID NO:1 in an individual, comprising obtaining a sample comprising a Spastin polypeptide from the individual and determining the size of the Spastin polypeptide, classified in class 435, subclass 7.1.

Should Inventions I, II, III, IV, V or VI be elected, applicant is required to select one nucleic acid sequence from claim 1 and one primer nucleic acid sequence from claim 23. Each nucleic acid sequence, absent factual data to the contrary, is a distinct nucleic acid. This is not species election.

Should Inventions VII be elected, applicant is required to select a nucleic acid or a polypeptide because they are physically and functionally distinct chemical entities and produce different effect for treating a neurodegenerative disorder.

2. The inventions are distinct, each from the other because of the following reasons:

The nucleic acid, nucleic acid construct and the host cell of Invention I is related to protein of Invention III because the protein can be produced by the expression in the cell. The inventions are distinct because they are physically and functionally distinct chemical entities and the protein can be made by another process such as isolation procedure from natural source.

The nucleic acid of Invention I is distinct from the antibody of Invention IV because the two groups of products are physically and functionally distinct chemical entities, and the antibody of Invention IV cannot be made by the product of Invention I.

The product of Invention I and the methods of Invention II, V and VII (for nucleic acid part) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Invention II, V and VII are alternative processes of use of the nucleic acid of Invention I.

The product of Invention I is distinct from the methods of Invention VI, VII (for the protein part) and VIII because the product of Invention I can be neither made by nor used in the methods of Invention VI, VII and VIII.

The method of Invention II and the product of III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be isolated from natural source.

The method of Invention II is distinct from the methods of Inventions V-VIII because the method steps and outcomes are wholly different between Inventions II and V-VIII, therefore Inventions II and V-VIII are patentably distinct.

The protein of Invention III is related to the antibody of Invention IV by virtue of being the cognate antigen, necessary for the production of the antibody. The inventions are distinct because they are physically and functionally distinct chemical entities and because the protein can be used in another and materially different process from the use for production of the antibody such as to assay or purify the cognate receptor of the protein or in assays for the identification of agonists or antagonists of the receptor protein.

The product of Invention III and the methods of Inventions VII (for the protein part) and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions VII and VIII are alternative processes of use of the polypeptide of Invention III.

The product of Invention III is distinct from the methods of Inventions V and VI because the product of Invention III can be neither made by nor used in the methods of Inventions V and VI.

The product of Invention IV is distinct from the methods of Inventions II, V, VII and VIII because the product of Invention IV can be neither made by nor used in the methods of Inventions II, V, VII and VIII.

The product of Invention IV and the method of Invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of Invention IV can be used to isolate the polypeptide by affinity chromatography.

The methods of Inventions V-VIII are distinct from each other because the method steps and outcomes are wholly different among Inventions V-VIII, therefore Inventions V-VIII are patent distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and because inventions I-VIII require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Lisa Treannie on February 19, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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February 9, 2002

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600